

REMARKS

An Office Action was mailed in the above-captioned application on December 11, 2007. Claims 38, 40-42, 62 and 75 were pending in the application, and claims 38, 40-42, 62 and 75 have been rejected. This Amendment and Response is submitted in response to the Office Action of December 11, 2007. Claims 38, 41 and 42 are hereby amended, new claims 76, 77 and 78 have been added, and claims 40, 62 and 75 are cancelled without prejudice and without intending to publicly dedicate any patentable subject matter. Applicant reserves the right to prosecute cancelled subject matter in a continuing application. Support for the amendment to claims 38, 41 and 42 and for new claims 76, 77 and 78 can be found in the specification, claims and drawings as originally filed. No new matter has been added by these amendments or by these new claims. As set forth more fully below, reconsideration and withdrawal of the Examiner's rejections is respectfully requested.

The Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 38, 40 and 75 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner argues that the instant specification does not convey with reasonable clarity to those skilled in the art that the Applicant, as of the filing date sought, had possession of the claimed invention.

The Examiner has also rejected claim 75 by arguing that this claim refers to claims 38 and 40 in the alternative (Office Action, page 5). Applicant notes that claim 75 has been cancelled, thus making this rejection moot.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species of that genus. MPEP § 2163.05. A "representative number of species" means that the species which are adequately described are representative of the entire genus. *Id.* While disclosure of only a single species within a genus can adequately describe an entire genus only in certain, limited situations (*see Enzo Biochem,*

323 F.3d at 966, 63 USPQ2d at 1615), the "use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds" *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973). Applicant respectfully disagrees with this rejection; however, in the interest of expediting prosecution, claim 38 has been amended and claim 40 has been cancelled. Specifically, claim 38 has been amended to include the limitations of claim 40 and some of the limitations of claim 41.

In the Office Action, the Examiner states that:

Applicant's claims are drawn to a broad genus of protein variants having a F-V mutation in a binding domain of a cytokine (claim 38), wherein the cytokine is a 4-alpha helix bundle cytokine (claim 40). Neither these claims [nor] the specification adequately describe F-V mutations in the genus of claimed variants such that one of skill in the art would be aware that Applicant was in possession of the entire genus of protein variants at the time the application was filed.

Office Action, page 4. However, later in the Office Action (in the rejection under 35 U.S.C. § 112, Second Paragraph), the Examiner states:

It is noted that the specification recites SEQ ID NOs for the proteins recited in claim 41 (see pp. 18-20).

Applicant notes that claim 38 has been amended to include the proteins recited in claim 41. In light of this amendment, claim 38 now recites proteins that all contain SEQ ID NOs, as noted by the Examiner. These SEQ ID NOs were included with the specification at the time of filing. Therefore, claim 38, as amended, contains subject matter which was described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicant had possession of the claimed invention at the time of filing. Reconsideration and withdrawal of this rejection is respectfully requested.

The Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claims 38, 40-42 and 75 under 35 U.S.C. § 112, second paragraph, “as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.” Office Action, page 5. Specifically, the Examiner argues that claim 42 does not set forth whether the claimed residues are to be determined from the sequence of the wild-type protein with its signal sequence intact or from the mature protein, which has had the signal sequence removed. Additionally, the Examiner has advised the Applicant to compare claim 42 to claim 62, noting that claim 62 sets forth a specific SEQ ID NO that clearly sets forth the starting point of the sequence.

In response to this rejection, claim 41 has been amended to recite that each cytokine is the wild-type protein. Additionally, claim 42 has been amended as the Examiner suggests, to recite each of the protein variants in view of their SEQ ID NO so as to more clearly reflect the starting point residue for each claimed protein variant. These amendments therefore address and overcome each of the matters raised by the Examiner. Reconsideration and withdrawal of this rejection is respectfully requested.

The Rejection Under 35 U.S.C. § 102(e)

The Examiner has rejected claims 38, 40-42, 62 and 75 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2005/0220800 to Roberts et al. (“Roberts”). Specifically, the Examiner argues that Roberts teaches a TPO variant at paragraph 160 and Fig. 9, and a composition comprising the protein at paragraph 24. Claims 62 and 75 have been cancelled, rendering this rejection moot as it applies to them.

It is well established that, for a reference to anticipate, it must describe the claimed invention in sufficient detail to place the public in possession of it. *In re Donahue*, 766 F.2d 531, 533 (Fed. Cir. 1985). This standard is met only if “a single, prior art document describe[s] every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.” *Advanced Displays*

Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000); *see also Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1057 (Fed. Cir. 2003). But disclosure of each element by the single prior art reference is not enough; the Court of Appeals for the Federal Circuit has long held that “[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim.” *Finisar Corporation v. The DirecTV Group, Inc., et al.*, 2008 U.S. App. LEXIS 8404, *27-28 (Fed. Cir. April 18, 2008) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)).

Applicant respectfully disagrees with this rejection. Roberts discloses methods for producing variant proteins having reduced allergenicity comprising the steps of: a) obtaining a naturally-occurring protein and preparing fragments of the naturally-occurring protein; b) contacting the fragments with a first solution comprising naive human CD4+ or CD8+ T-cells and differentiated dendritic cells; c) identifying an epitope region of the naturally-occurring protein by measuring the ability of the protein fragments to stimulate proliferation of the naive human CD4+ or CD8+ T-cells; and d) modifying at least one amino acid in the identified epitope region to produce a variant protein.

In contrast, the present invention does not create or utilize fragments of a naturally-occurring protein, does not contact protein fragments with naive CD4+ or CD8+ T-cells or differentiated dendritic cells, and does not measure the ability of protein fragments to stimulate the proliferation of naive CD4+ or CD8+ T-cells. Therefore, Roberts fails to disclose each and every element of claims 38, 41 and 42 and fails to disclose the invention recited in claims 38, 41 and 42 in sufficient detail to place the public in possession of it. Roberts therefore can not, and does not, anticipate claims 38, 41 and 42. Reconsideration and withdrawal of this rejection is respectfully requested.

Appl. No. 10/519,390

Amendment and Response dated June 11, 2008

Based at least upon the foregoing, Applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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